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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,686	11/29/1999	GUSTAV HAGEN	BAYER10.203	8382

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NORRIS MCLAUGHLIN & MARCUS
220 East 42nd Street
30th floor
New York, NY 10017

EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	PAPER NUMBER
1652	30

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/424,686	HAGEN ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-46* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The Response to Restriction Requirement filed on January 30, 2003, as paper No. 24 is acknowledged. Claims 14-46 are pending in the Application; claims 14 (e), 20, 24 in part, 30, 34 in part, 40, 44 in part, 45 in part, and 46 in part, are the subject of this Office Action. Claims 14 in parts a-d and f-h, 15-19, 21-23, 24 in parts related to part a-d and f-h of the base claim 14, 25-29, 31-33, 34 in part related to parts a-d and f-h of the base claim 14, 35-39, 41-43, 44 in part related to parts a-d and f-h of the base claim 14, 45 in part related to parts a-d and f-h of the base claim 14, and 46 in part related to parts a-d and f-h of the base claim 14, are withdrawn from consideration as drawn to the nonelected invention.

The examiner acknowledges computer readable and paper forms of sequence listing, filed on February 6, 2003. The disk was melted during security irradiation. A new disk was sent to the examiner on March 13, 2003. This disk was not accompanied by the statement that paper sequence listing and the computer readable are the same, and that computer and/or paper listing submitted includes no new matter.

DETAILED ACTION

1. Election/Restriction

Applicant's election with traverse of group V, claims 14 (e), 20, 24 in part, 30, 34 in part, 40, 44 in part, 45 in part, and 46 in part in Paper No. 24 is acknowledged. The traversal is on the following ground(s):

1. "In the original claims as filed, claim 1 was drawn to human telomerase, and 'its functional equivalents, its variants, and its catalytically active fragments"(page 3, line 2).

2. "Further on page 4 of the Office Action of August 15, 2001, Examiner indicates that the 'hTC protein variants named variants 1-4 in Example 11 satisfied the enablement requirement. This included the DNA encoding these variants. Therefore, in the previous restriction requirement, Examiner had already acknowledged these sequences should be examined together" (page 3, line 11).

3. "The restriction in this application targets highly related nucleic acids having identical utilities" (page 4, line 13).

Applicants' arguments have been fully considered, but are not found persuasive for the following reasons.

Firstly, claims 14-46 are not amended claims but a new claims. Referring to claim 1, as originally filed, is at this stage of prosecution moot, because claim 1, was generic and recited no species. Therefore, restriction between species was not possible.

Secondly, the fact that protein variants named variants 1-4 in Example 11 satisfy the enablement requirement does not mean that these variants satisfy requirement of unity of invention, i.e. do not require restriction.

Thirdly, although the nucleic acid molecules towards which claim 14 is directed are encompassed by the genus of eucaryotic telomerase, they do not have the same

chemical structure, and they do not have identical utilities, because they do not necessary have the same catalytical function of telomerase. Those skilled in the art realize, that splice variants, and recombinant variants and mutants may retain or lose their telomerase catalytic function, or may acquire a new function.

As stated in restriction requirement, paper No. 23, the inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons stated in restriction requirement, paper No. 23, as well as for the reason given above.

The special technical feature of Groups I-VIII seems to be the catalytically active subunit of eucaryotic telomerase. However, the catalytically active subunit of eucaryotic telomerase of group I-IV, sequences recited by claim 14 a) to 14 d) are not contribution over the prior art, because the human, *Euplotes*, *S. pombe* telomerase, as well as the variant of human telomerase without intron beta, nucleotides 2345-2526 of SEQ ID NO: 1 of the instant application, have been disclosed in the US Patents No. 6,093,809; 6,309,867; and 6166,178, respectively; see also rejection of claim 1 under 35 USC section 102, in the first Office Action on merits, paper no. 10.

In addition, the special technical features of Groups V-VIII seems to be a variant of the catalytically active subunit of human telomerase, however, each of the variant of Groups I and V-VIII is independent chemical entity having its chemical structure and biologic properties.

In conclusion, technical features of Group I -VIII are different and unity of invention is lacking with regard to Group I-VIII.

For all above enumerated reasons restriction between Groups I-VIII is proper and is therefore made FINAL.

2. Lack of compliance of nucleotide sequence disclosure with 37 C.F.R. 1.821-1.825

Examiner acknowledges transmittal of Computer Readable Form (CFR) and Paper Sequence Listing on February 6, 2003. The disk was melted during the irradiation for security purposes (see the attached CRF Problem Report).

The new disk was sent to the examiner on March 13, 2003. This disk was not accompanied by the statement that paper sequence listing and the computer readable form are the same and that computer and/or paper listing submitted includes no new matter. In addition, this CRF contains numerous errors as indicated in the Raw Sequence Listing Error Report enclosed to this office Action.

In addition, several primer sequences are recited in the specification, page 15, 33 and further, but they are not identified by their sequence identification numbers. These primer sequences are also missing in the sequence listing, computer readable or paper forms.

Thus, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the

requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

2. Objections

2.1. Specification

The specification is objected to for new matter. The paper and computer readable sequence listing contain SEQ ID NO: 1 that is different from SEQ ID NO: 1 as filed. The original SEQ ID NO: 1 is a DNA molecule consisting of 4042 nucleotides encoding human telomerase; see Fig. 1 and originally filed paper sequence listing. The SEQ ID NO: 1 filed on Feb.6, 2003 consist only of 3470 nucleotides.

Description of Fig. 2 is confusing. Applicants write, "The DNA sequence depicted in Fig.1 can be completely translated from Position 64 to Position 3461 into an amino acid sequence." Actually, the open reading frame consists of nucleotides 63-3458, and three nucleotides 3459-3461 are a stop codon.

The specification is objected for numerous capitalizations of nouns and adjective, for example, page 1 line 5, page 14, line 22.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

3. Rejections

3.1. 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are reciting the term "an antisense nucleic acid", however neither the claims nor the specification define the term "an antisense nucleic acid". It is unknown whether the anitsense nucleic acid must be full length complement or only fragment.

The claims are also reciting the phrase "that binds to the nucleic acid sequence", however neither the claims nor the specification define the conditions of binding, thus rendering the claim indefinite. The claim should specifically recite the hybridization conditions used for binding the antisense nucleic acid sequence.

3.2. 35 USC, section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Lack of written description

Claim 14, 24, 34, 44, 35 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a variant nucleic acid sequence of SEQ ID NO: 1 wherein nucleotides 2184 to 2219 of SEQ ID NO: 1 have been deleted; to protein encoded by said variant, vector comprising said variant, host cells and recombinant production of the variant protein. However, SEQ ID NO: 9 that sets forth said variant is 4006 nucleotides long and SEQ ID NO: 1 is actually 3470 nucleotides long. As such, the actual sequence of the variant DNA molecule, and the encoded protein are unclear.

3.3. ***35 USC section 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 34 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech et al in the US Patent No. 6,093,809 ('809) issued on July 25, 2000, with priority to Oct. 1996.

Claims 34 and 40 to an antisense nucleic acid sequence that is antisense to SEQ ID NO:1, wnerein nucleotides 2184 to 2219 have been deleted.

Cech et al disclose the human telomerase cDNA in SEQ ID NO:224 of the '809. The sequence itself or many of primers and fragments disclosed in the patent can be used as the nucleic acid molecule that is antisense to the variant disclosed in the instant application.

3. Conclusion

All claims are rejected due to the sequence listing errors, however the nucleic acid sequence of SEQ ID NO: 9, representing variant of Claim 14 (e) as originally filed, is free of prior art and nonobvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

Art Unit 1652

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600

Application No.: 09/424,686

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a Sequence Listing as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the Sequence Listing in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the Sequence Listing in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up Raw Sequence Listing.

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the Sequence Listing is not the same as the computer readable from of the Sequence Listing as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or **substitute** computer readable form (CRF) copy of the Sequence Listing.

☒ An initial or **substitute** paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For Patent software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE